DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94599d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

APR 5 2004

WARNING LETTER

FEDERAL EXPRESS

Mr. Choon K. (K.C.) Choong, President
Electro Therapeutic Devices, Inc.
470 Hood Road, Unit 14
Markham, Ontario
Canada

Dear Mr. Choong:

During the inspection of your establishment located in Markham, Ontario, Canada, on December 1, 2003, our investigator determined that your firm is the repackager/relabeler of the ACCU-O-MATIC SP Series Transcutaneous Electrical Nerve Stimulators (TENS) devices and the ITO ADDIQUIP Acupuncture Needles. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 351(h).

Our inspection revealed that these devices are not in conformance with the Quality System (QS) regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulation, Title 21 CFR, Part 803. Your devices are adulterated within the meaning of Section 501(h) and misbranded within the meaning of Section 502(t)(2) of the Act.

Quality System Regulation

The investigator noted the following violations of the QS regulation as follows:

1. Your firm failed to maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198(a). For example, complaint handling procedures for receiving, reviewing, and evaluating complaints have not been established.

2. Your firm failed to establish and maintain procedures to control labeling activities as required by 21 CFR 820.120. For example, your firm has not established labeling procedures.

3. Your firm failed to establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements as required by 21 CFR 820.200(a). For example, your firm has not established servicing procedures.

4. Your firm failed to establish and maintain procedures for implementing corrective and preventive actions and verifying or validating those corrective actions as required by 21 CFR 820.100(a). For example, your firm has not established: (a)

the procedures for implementing corrective and preventive actions; (b) the procedures addressing verification or validation of corrective and preventive actions; and (c) the procedures addressing submission of information on identified quality problems and corrective and preventive actions for management review.

5. Your firm failed to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. For example, your firm did not: (a) establish procedures to conduct quality audits; and (b) conduct quality audits to verify that the quality system is effective in fulfilling quality system objectives. As a repackager/relabeler, your firm needs to develop procedures and conduct audits only for the activities which you are performing, such as the labeling, packaging, and the service/repair of devices.

6. The management of your firm with executive responsibility failed to review the suitability and effectiveness of the quality system and at defined intervals as required by 21 CFR 820.20(c). For example, your firm did not: (a) establish procedures for management review; and (b) conduct management reviews defined intervals. As a repackager/relabeler, your firm needs to develop procedures and conduct reviews only for the activities which you are performing, such as the labeling, packaging, and the service/repair of devices.

Medical Device Reporting (MDR)

The investigator noted that there was a failure to comply with a requirement prescribed under Section 519 of the Act as follows:

7. Your firm failed to establish and maintain written MDR procedures as required by 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the list of Inspectional Observations (Form FDA 483) issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Given the serious nature of these violations of the Act, the ACCU-O-MATIC SP Series TENS devices and ITO ADDIQUIP Acupuncture Needles repackaged/relabeled by Electro Therapeutic Devices, Inc., are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA may take steps to refuse these products, know as "detained without physical examination," upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from detention, you should provide a written response to this Warning Letter (as described below) and correct the violations described in this letter. We will notify you if your response is adequate, and we may need to reinspect your facility to verify that the appropriate corrections have been made. In addition, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of government contracts.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to: Mr. Donald W. Serra, Cardiovascular and Neurological Devices Branch, HFZ-341, Division of Enforcement B, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. If you have any questions concerning this matter, you may contact Mr. Serra at 301-594-4648, ext. 118.

Sincerely yours,

Larry D. Stern for

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health